UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**CIVIL ACTION NO. 2:12-md-02327**
This Document Applies To All Cases in Wave 3	**MDL No. 2327** Judge Joseph R. Goodwin

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF HARRY JOHNSON, JR., M.D.

This Memorandum applies to all cases in Wave 3. Pursuant to Federal Rule of Evidence 702, Plaintiffs hereby seek to limit certain opinions and testimony proffered by Defendant Johnson & Johnson and Ethicon, Inc.'s (hereinafter "Defendants") expert Harry Johnson, Jr., M.D. on their TVT product. In support of their Motion, Plaintiffs respectfully show the Court as follows:

I. INTRODUCTION

Harry Johnson, Jr., M.D. ("Dr. Johnson") is a diplomate of the American Board of OB/GYN and is board certified in the subspecialty of Female Pelvic Medicine and Reconstructive Surgery.[1] However, Dr. Johnson offers opinions in these cases that are beyond his field of expertise, not supported by reliable methodology, or not supported by reliable application of methodology. Dr. Johnson has proffered an expert report on Defendants' TVT product. *See generally* Ex. A. Dr. Johnson opines, *inter alia*, that Defendants' product is safe; that voluminous medical literature supports the safety of Defendants' product; that Defendants' product does not suffer from undisclosed defects; and that all pelvic floor surgeons would be aware of any risks

[1] *See General Expert Report of Dr. Harry Johnson, Jr., MD Regarding TVT* attached to Plaintiffs' Motion to Limit the Opinions and Testimony of Harry Johnson, Jr., M.D. (hereinafter the "Motion") as **Exhibit A**; *see also Harry Wallace Johnson, Jr., M.D. Curriculum Vitae*, attached to Plaintiffs' Motion as **Exhibit B**.

associated with using Defendants' product. In arriving at these conclusions, Dr. Johnson sets forth opinions that are: (a) irrelevant as they relate to Defendants' TVT-O product, not the TVT product as issue in these cases; (b) based on unknown facts or data as Dr. Johnson's reliance list and supplemental reliance lists are deficient; or (c) unsupported by reliable methodology, reliable application of methodology or are outside of Dr. Johnson's area of expertise.

As such, Dr. Johnson offers these opinions despite lacking specialized knowledge of these topics, without utilizing a proper methodology, or without reliably applying methodology as required by Federal Rule of Evidence 702. All of Dr. Johnson's opinions and testimony suffering from these defects should be excluded or limited.

II. LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403, and 104. *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony). The trial judge acts as a gatekeeper for scientific, technical, and other specialized knowledge. *See Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579, 588 (1993); *Kumho Tire Co., v. Carmichael*, 526 U.S. 137, 141 (1999).

III. ARGUMENT

Dr. Johnson's medical training in the fields of obstetrics and gynecology do not automatically render his opinions on other ancillary issues admissible. *See Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001). Indeed, each individual opinion he

offers must satisfy the requirements of the Federal Rules of Evidence to be admissible. *See, e.g.*, *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997); *see also Daubert*, 509 U.S. at 579.

As a threshold matter, an expert witness "must have 'knowledge, skill, experience, training, or education' in the subject area in which he will testify." *Bombardiere v. Schlumberger Tech. Corp.*, 934 F. Supp. 2d 843, 846 (N.D. W. Va. 2013) (quoting Fed. R. Evid. 702). In the context of Rule 702, knowledge "connotes more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. Trial courts must ensure that a purported expert witness "is not merely parroting the opinions of others, but that the *matters upon which she will opine are clearly within her area of expertise*." *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D.N.C. 2007) (emphasis added). Thus, a fundamental prerequisite to admission of an expert's opinion is that the opinion be related to that expert's specialized knowledge. *See, e.g.*, *U.S. v. Johnson*, 54 F.3d 1150, 1157 (4th Cir. 1995). Under this clear standard, Dr. Johnson, just like any other expert witness, may only testify on subjects within his area of expertise.

Additionally, Dr. Johnson's opinions must be based upon reliable and proper methods. *See Coleman v. Union Carbide Corp.*, 2013 WL 5461855, at *17 (S.D. W. Va. 2013) (holding that expert testimony must be reliable and relevant to be admissible). As this Court has recognized in a related MDL:

> Just because an expert may be "qualified . . . by knowledge, skill, experience, training or education" does not necessarily mean that the opinion that the expert offers is "the product of reliable principles and methods" or that the expert "has reliably applied the principles and methods to the facts of the case."

Cisson v. C.R. Bard, Inc., 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013). The burden is on the Defendant to show that *each* of Dr. Johnson's opinions have a reliable foundation based on stated principles and methods. *See Daubert*, 509 U.S. at 597. Opinions which are not within Dr.

Johnsons's area of expertise, which are not the product of reliable principles and methods, or which are not the product of reliable application of principles and methods should be excluded.

A. All Opinions Proffered by Dr. Johnson on TVT-O, Rather than TVT, are Irrelevant and Should be Excluded.

As with any other form of proffered evidence, expert testimony must be relevant to be admissible. *Coleman*, 2013 WL 5461855, at *17. Here, Dr. Johnson offers a plethora of opinions related to Defendants' TVT-O, *see, e.g.*, Ex. A at 14 ("In 2006, J.L. Lynn published findings on 100 consecutive women undergoing a TVT-O procedure . . . [t]he conclusion was TVT-O was a safe and effective treatment for female stress urinary incontinence"), despite acknowledging that these consolidated cases involve Defendants' TVT product, not TVT-O:

> Q. Okay. And that expert report [referring to Ex. B] expresses opinions on the TVT product?
>
> A. That's correct.
>
> Q. And on the TVT-O product?
>
> A. Yes.
>
> Q. Okay. Would you agree that the Mullins consolidation involves cases only regarding the TVT product?
>
> Mr. Combs [Defendants' counsel]: Dr. Johnson may not know that. I'll stipulate that it does, but you're welcome to ask him about it.
> . . .
>
> Q. I mean, do you know that, Dr. Johnson?
>
> A. That's my understanding.
> . . .
>
> A. I'm going to offer opinions about TVT in these six cases.
>
> Q. Okay. So in these six cases, you won't offer any opinions related to TVT-O's safety or efficacy?
>
> A. Only if a question about TVT-O were to come up.

Deposition of Harry Johnson, Jr., M.D. dated July 14, 2016 at 5:11-21, 24-25; 7:5-11, attached to Plaintiffs' Motion as **Exhibit C**. Both Dr. Johnson and his attorney agreed, in deposition, that these cases only involve Defendants' TVT product, not TVT-O; and therefore, any opinions in Dr. Johnson's expert report related to TVT-O are irrelevant and should be excluded. *See also* Pretrial Order No. 184 (consolidating cases for trial in which plaintiffs were implanted with TVT). Moreover, if Dr. Johnson were permitted to opine on the safety and efficacy of Defendants' TVT-O, it is likely the jury would be confused with regard to the safety and efficacy of Defendants' TVT as none of the plaintiffs in these cases were implanted with TVT-O.

B. All Opinions Proffered by Dr. Johnson Based on Unknown Facts or Data Should be Excluded.

In his expert report, Dr. Johnson offers a number of uncited opinions and conclusions. *See, e.g.*, Ex. A at 5 ("Up to 50% of women may improve enough to forego surgical treatment initially, however >90% of these patients remain incontinent and > 60% [sic] may subsequently seek surgical management" [lacking citation to authority]). A conclusion with specificity such as this requires a citation to authority, or at the very least, a reliance list that directs Plaintiffs to the basis for such an opinion. *See* Fed. R. Civ. P. 26(a)(2)(B)(i) and (ii) (requiring disclosure of an expert's opinions, including the basis for such opinions, and the facts or data considered by the witness in forming such opinions). Dr. Johnson has offered neither, and therefore, all uncited opinions proffered by Dr. Johnson should be excluded as Plaintiffs have no way of determining the basis for such opinions, let alone an ability to prepare to rebut these opinions at trial.

Dr. Johnson, admitted in deposition, that his reliance list (and supplemental reliance list) is not actually a disclosure of the basis, facts or data he relied upon in forming his opinions; but rather, is simply a list of all documents sent to him by Defendants' attorneys:

Q. Okay. And what are these?

A. It's a reliance list and supplemental reliance list?

Q. Okay. And so are all of the materials you listed in the reliance list and supplemental reliance list materials you relied on in forming your opinions on the TVT product?

A. The materials that I relied on are within this list.

Q. Okay. And so there are additional materials on the list that you did not rely on?

A. No. There's -- there are things in this list that I didn't review that I didn't feel were important to me.

Q. Okay. And so the materials on the list were provided to you by Ethicon's attorneys?

A. By Butler Snow.

Q. Okay. And Butler Snow is the law firm -- one of the law firms that represents Defendants, correct?

A. Yes.

Q. And so they sent over various materials for you to review?

A. I mean, my understanding is they sent everything on these reliance lists.

Q. And then you reviewed some of it, relied on that to form your opinions; is that fair?

A. Yes.

Q. And then some of it you didn't review because you didn't think it was relevant or necessary?

A. Yes.

Q. Okay. And what is your understanding of -- how would you define a reliance list?

. . .

A. It would be materials that I can review and rely on to help me write a report and reference the medical literature involving the report that I would be writing.

Q. Okay. And so why, then, did you include information on the reliance list that you didn't, in fact, rely on in forming your opinions on the TVT product?

> A. Well, this list is a list of everything that I was sent, so I just provided a complete list of materials that I was sent.

Ex. C at 8:8-10:6 (objections omitted). Moreover, Dr. Johnson admitted that he could have provided a proper reliance list, *i.e.*, there were no extenuating circumstances that may have provided a partial or full justification for his failure to do so:

> Q. Okay. So is it possible -- would it be possible for you, then, to go through Exhibit 4 and 5, the reliance list and supplemental reliance, and pare it down to the -- just the materials you actually did rely upon in forming your opinions on the TVT?
>
> A. Well, I don't think that would be possible because a lot of the material I reviewed and just formed opinions over a long period of time, not specifically for this report. So I reviewed literature in addition to performing the report that's part of this literature --
>
> Q. But you would --
>
> A. -- or medical science.
>
> Q. But you would recognize any materials on there you haven't read before, correct?
>
> A. For the most part, yes.

Ex. C at 10:15-11:6. As such, the failure of Dr. Johnson and Defendants to provide a proper reliance list, in conformity with the Federal Rules of Civil Procedure, was the product of neglect not allowable under any provision of the Rules. The effect of this failure is prejudicial to Plaintiffs as Plaintiffs are unable to determine the basis for any of Dr. Johnson's opinions expressed in his expert report, save those opinions that are cited. The scope of this problem is not hyperbole: Dr. Johnson served a reliance list that is 43 pages long and a supplemental reliance list that is 46 pages long, with at least 1,000 line items combined.[2] Plaintiffs should not be forced to search for a needle

[2] *See Reliance List in Addition to Materials Referenced in Report* attached to Plaintiffs' Motion as **Exhibit D**.

in a haystack in an effort to prepare for trial. As such, all of Dr. Johnson's uncited opinions expressed in his expert report should be excluded.[3]

C. All Other Opinions Proffered by Dr. Johnson that are Not Supported by Reliable Methodology, Reliable Application of Methodology or Outside his Area of Expertise Should be Excluded.

Dr. Johnson opines on many subjects that, if not excluded for the reasons stated above, should be excluded as they are not supported by reliable methodology, reliable application of methodology or are outside his area of expertise.

1. Dr. Johnson Should Not be Permitted to Opine that Defendants' TVT is the "Gold Standard."

Dr. Johnson opines that: "Since 2000, the TVT procedure has been rapidly accepted and has become the gold standard for treatment of stress urinary incontinence." Ex. A at 13. The term "gold standard" implies various traits about Defendants' product, not the least of which is that Defendants' product is the first choice for surgeons when treating SUI. This implication runs the serious risk of confusing and misleading the jury in that the jury may discount other surgical procedures proffered by Plaintiffs as safer alternatives. After all, why would any patient or physician forego a treatment option when an expert states that option is the "gold standard?" Moreover, in deposition, Dr. Johnson equivocated when stating the basis for his opinion that Defendants' TVT product is the "gold standard":

Q. What does gold standard mean?

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[3] Plaintiffs note that it would be well within the Court's discretion to exclude Dr. Johnson's testimony entirely for failing to comply with the Federal Rules on expert disclosures. *See, e.g., Meyers v. Nat'l R.R. Passenger Corp.*, 619 F.3d 729, 734 (7th Cir. 2010) (noting that the purpose of expert disclosures is to allow opposing side to prepare a response, and the consequence for noncompliance with Rule 26(a)(2)(B) is "exclusion of an expert's testimony" unless the failure was substantially justified or harmless). Here, Defendants' failure to comply with Rule 26(a)(2)(B) is neither substantially justified nor harmless, and therefore, Dr. Johnson's testimony may be excluded in its entirety.

> A. That would be the most commonly performed procedure for treatment of urinary incontinence or the most widely accepted common treatment.
>
> Q. So if there's treatment for SUI -- and in this case, we're referring to the TVT treatment -- if it's the most common or the most widely accepted, then it's the gold standard?
>
> A. It's the most commonly performed procedure in the world, the TVT is.
>
> Q. So that makes it the gold standard?
>
> A. I think so.

Ex. C at 64:7-18. Dr. Johnson "thinks so" when describing the basis for his opinion that TVT is the "gold standard" treatment for stress urinary incontinence. This type of opinion is hardly scientific, is misleading and is exactly the type of unreliable opinion that is proper for exclusion under *Daubert*.

2. Dr. Johnson Should Not be Permitted to Testify Regarding the FDA Section 510(k) Process.

Dr. Johnson opines: "TVT was introduced in the United States by Ethicon in 1998 after receiving 510K [sic] clearance by the FDA." Ex. A at 11. However, in deposition, Dr. Johnson admitted he is unfamiliar with the FDA's Section 510(k) process:

> Q. What is 510 clearance -- or excuse me -- 510(k) clearance?
>
> A. I'm not an expert on government forms, but my general understanding is that's what you go through with the FDA to introduce a product to market.
>
> Q. Okay. So you don't have any experience in assisting medical device manufacturers with obtaining 510(k) clearance?
>
> A. I don't.

Ex. C at 63:14-23. Dr. Johnson's unfamiliarity with the FDA's Section 510(k) process should preclude him from opining that Defendants' product was introduced to market after receiving 510(k) approval as the jury, hearing this statement from an expert, may equate Dr. Johnson's

opinion with a conclusion that the FDA's 510(k) process signifies that Defendants' product was safe.

A wealth of authority holds that the Section 510(k) process is not related to product safety or efficacy, as well as abundant case law holding that there are no safety requirements imposed by way of the Section 510(k) process.[4] The FDA itself explained the difference between the Section 510(k) process and the more rigorous "premarket approval" process in an amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, 376 F.3d 163, 167 (3d Cir. 2004) ("A pre-market notification submitted under 510(k) is thus entirely different from a [premarket approval,] which must include data sufficient to demonstrate that the device is safe and effective").

Thus, Dr. Johnson's unfamiliarity with the 510(k) process falls short of the "specialized knowledge" required by Rule 702. Because Dr. Johnson is not an expert on FDA regulations, he should be prevented from testifying and confusing the jury as to the significance of Section 510(k) approval of Defendants' TVT product.

3. Dr. Johnson's Opinion that Defendants' IFU is Adequate Should be Excluded.

Dr. Johnson opines: "The IFU properly warns physicians of the adverse reactions that may occur with TVT . . . ." Ex. A at 35. Dr. Johnson admitted in deposition that additional complications

[4] *See, e.g., Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008) ("[D]evices that enter the market through § 510(k) have 'never been formally reviewed under the MDA for safety or efficacy"); *Smith v. Depuy Orthopaedics, Inc.*, 2013 WL 1108555, at *4 (D.N.J.2013) ("The 510(k) process is different from PMA because under the 510(k) process, the FDA must find that a new device is ''substantially equivalent' to another device exempt from premarket approval' instead of making a determination regarding the safety and effectiveness of the device….The device is not 'formally reviewed ... for safety or efficacy.'").

could have been listed in Defendants' IFU, which is directly contrary to his opinion described in his expert report:

> Q. Sure, but the IFU then also lists transitory local irritation at the wound site. Couldn't that occur with any pelvic floor surgery?
>
> A. Yes.
>
> Q. So if that's listed on the IFU, wouldn't it also be appropriate to list recurrent urinary tract infections?
>
> A. Again, it's not specific. It wouldn't be -- it's not specific for a mesh procedure, but it's something that can occur with any pelvic floor surgery, which a mesh procedure is. So it wouldn't be wrong to list it.
>
> Q. And so then it wouldn't be wrong to list dyspareunia?
>
> A. You could list that.

Ex. C at 76:25-77:17 (objections omitted). While Dr. Johnson admitted that recurrent urinary tract infections and dyspareunia could be listed in Defendants' TVT IFU, neither of these potential complications are in fact listed in the IFU. *See* Ex. A at 24-27. Therefore, Dr. Johnson's opinion that Defendants' IFU is adequate is contrary to his own opinion stated in deposition and should be excluded. Additionally, nowhere in Dr. Johnson's expert report or curriculum vitae does he list any experience or credentials that render him qualified to opine on the adequacy of Defendants' IFU.

Dr. Johnson also opines on Defendants' "2015 TVT and TVT-O IFU Change," Ex. A at 28-29, even though he acknowledges: "Because all of the cases in Wave II and the Consolidated cases (Mullins) involved implantations prior to October 2015, I will confine my discussions to the pre-2015 IFU except where specifically noted." Ex. A at 23. The "2015 TVT and TVT-O IFU Change" is, by Dr. Johnson's own admission, irrelevant; and therefore, any opinions on this issue

should be excluded. Additionally, for the reasons stated above, any opinions related to TVT-O should also be excluded on separate relevance grounds.

4. Dr. Johnson's Opinions Based on the SISTEr and E-SISTEr Trials are Irrelevant and Should be Excluded.

Dr. Johnson opines: "The SISTEr Trial, reported by Albo, et al. compared the Burch colposuspension to fascia sling" and "[t]he SISTEr and E-SISTEr data also revealed serious adverse events in the fascial sling group with serious events found in 13% and adverse events of all kinds in 63%." Ex. A at 7, 9. Dr. Johnson further explains the results of the SISTEr trial in some detail, noting that the Burch and fascial sling procedures use "rectus fascia," *i.e.*, these procedures use natural tissue not synthetic sling material. Ex. A at 9. Thus, any adverse events as related to the two procedures examined in the SISTEr and E-SISTEr trials are simply not relevant to the safety or efficacy of Defendants' TVT product as Defendants' product utilizes synthetic material.

Moreover, there exists the real possibility that Dr. Johnson' opinions in this regard will confuse the jury insofar as they may infer, consistent with Dr. Johnson's implication, that high adverse event rates with prior non-synthetic procedures logically lead to the assumption that Defendants' TVT product is safe. This conclusion does not follow as prior non-synthetic procedures may have had high incidents of adverse events (although Plaintiffs do not concede this fact) and Defendants' current products may still be unsafe. As the two propositions are not mutually exclusive and Dr. Johnson's expert report impermissibly conflates the two, these opinions should be excluded.

5. Dr. Johnson's Opinions that Rely Upon the Ford Cochrane Review 2015 Should be Excluded.

Dr. Johnson relies on the Ford Cochrane Review 2015 (the "Review") calling it one of the "highest level[s] of scientific evidence," for his opinions that "[t]here is a broad base of evidence

supporting the use of mid urethral slings" and "[t]here are over 2,000 publications in the scientific literature describing midurethral sling [sic] in the treatment of SUI." Ex. A at 19. Dr. Johnson's not so subtle implication is that the Review supports, in part, his ultimate conclusion that Defendants' TVT product is safe. Dr. Johnson's opinions strain the relevance of the scope and results of the Review and are misleading. First, the Review expressly noted: "Most of our results are based on *moderate quality* evidence. Most trials did not describe their methods clearly, thus leading to some degree of uncertainty in the findings. At present there are only a limited number of randomised controlled trials . . . This means that evidence about how effective and safe these procedures are in the longer term lags behind the evidence for them in the short and medium term (up to five years)."[5] Therefore, Dr. Johnson's statement that the Review is one of the "highest level[s] of scientific evidence" is misleading as the Review is premised upon "moderate" evidence. This opinion should be excluded.

More importantly, the Review "looked at the effects of mid-urethral sling operations when these two different *methods* [retropubic or transobturator] of performing the operations were used . . . The purpose of the review was to find out how effective these operations are in the treatment of stress urinary incontinence and to help determine the rate of potential complications or problems." Ex. E at 4 (emphasis added). Thus, the primary purpose of the Review was to compare surgical methods, not products. With respect to long-term safety outcomes, the Review cautions: "We encourage researchers to publish longer-term data to help increase the reliability of longer-term results in this area." Ex. E at 4. Dr. Johnson is attempting to shoehorn the results of the Review

[5] *See* Ford AA, et al., Mid-urethral sling operations for stress urinary incontinence in women (Review), Cochrane Database of Systematic Reviews, Issue 7 Art. No.: CD006375 (2015) at 4, attached to Plaintiffs' Motion as **Exhibit E** (emphasis added).

into forming a basis for his opinion that Defendants' TVT product is safe even though the results do not expressly or implicitly support this opinion, and as such, these opinions should be excluded.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request Dr. Johnson's opinions that are: (a) irrelevant as they relate to Defendants' TVT-O product, not the TVT product as issue in these cases; (b) based on unknown facts or data as Dr. Johnson's reliance list and supplemental reliance lists are deficient; or (c) unsupported by reliable methodology, reliable application of methodology or are outside of Dr. Johnson's area of expertise be excluded. With regard to Dr. Johnson's opinions that are unsupported by reliable methodology, reliable application of methodology or are outside of Dr. Johnson's area of expertise, Plaintiffs specifically request that all of Dr. Johnson's opinions that: (1) refer to Defendants' TVT as the "gold standard;" (2) relate to the FDA Section 510(k) process; (3) state that Defendants' IFU is adequate; (4) are based on the SISTEr and E-SISTEr trials; and (5) rely upon the Ford Cochrane Review 2015 be excluded.

Dated: December 15, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that December 15, 2016, a true and correct copy of Plaintiffs' Memorandum of Law in Support of Motion to Limit the Opinions and Testimony of Harry Johnson, Jr., M.D. was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

Dated: December 15, 2016

Respectfully submitted,

By: /s/ Aimee H. Wagstaff